

## CHAPTER 46 - Quality Assurance

### Section 46.1 Guidance for Use of Higher-Level Contract Quality Requirements in Acquisitions

#### 46.1.1 PURPOSE

This section establishes guidance for program personnel and Contracting Officers (COs) regarding the inclusion of higher-level contract quality requirements in applicable solicitations and contracts, and supplements the procedures and requirements contained in FAR 46.202-4 and FAR 52.246-11 (*Higher-Level Contract Quality Requirement*, Feb 1999). It also contains instructions for the use of the requisite FAR clause (FAR 52.246-11) for higher-level contract quality requirements (Appendices 46.1A and B), the QA Review Form (Appendix 46.1D) and provides a variety of "tailored" clauses that can be incorporated into contract actions (Appendix 46.1C). The FAR clause at 52.246-11 allows acceptable quality standards to be "tailored" to meet specific Agency needs.

#### 46.1.2 BACKGROUND

For information on EPA's quality assurance requirements for the collection, generation, use or reporting of environmental data, see [www.epa.gov/quality](http://www.epa.gov/quality); EPA Order 5360.1 A2, *Policy and Program Requirements for the Mandatory Agency-wide Quality System*; American National Standards Institute/American Society for Quality Control Standard E4-1994, *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs* (ANSI/ASQC E4); or contact the Quality Staff of the Office of Environmental Information.

This section was originally issued as a Procurement Policy Notice (PPN) 01-02 on March 20, 2001 by Judy S. Davis, Acting Director of the Office of Acquisition Management to Senior Resource Officials, OAM Division Directors, Regional Contracting Officer Supervisors, and Bruce Binder, OGC.

#### 46.1.3 AUTHORITY/APPLICABILITY

This section draws its authority from and supplements FAR Parts 46.202 and 52.246. This section applies to all solicitations, contracts (including simplified acquisitions), task orders, work assignments, and delivery orders that involve the collection, generation, use, or reporting of environmental data, and the design, construction, and operation of environmental technologies.

This section also applies to sole source purchases. The Project Officer, with approval of the Quality Assurance (QA) Manager of the organization sponsoring the work, may use "Other" in

Section III.b.1 of Appendix 46.1D to specify how the government will ensure, before award, the ability of the contractor to provide adequate quality products and services.

See [www.epa.gov/quality/examples.html](http://www.epa.gov/quality/examples.html) for examples of covered activities. This work is predominantly included in one of the following cost categories as set forth in the accounting and object classification structure:

25.05	Program Contracts
25.32	Research and Development Contracts
25.85/86	Administrative/Programmatic - Studies, Analyses and Evaluation Consulting Services

#### 46.1.4 DEFINITIONS

Environmental data are any measurements or information that describe environmental processes, locations, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.

Environmental Technology is an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term applies to hardware-based systems; however, it also applies to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

Higher-level Quality Requirements are those that apply to complex or critical items or when the technical requirements of the contract require control of such things as work operations, in-process controls, and inspection; or attention to such factors as organization, planning, work instructions, documentation control, and advanced metrology. For EPA, this type of quality requirement will apply to the collection, generation, use, or reporting of environmental data, and the design, construction, or operation of environmental technologies. Other types of quality requirements, as defined by FAR 46, apply to commercial items and supplies and services below the simplified acquisition threshold.

## **46.1.5 POLICY**

### **46.1.5.1 QA Review Form Requirements**

The QA Review Form is used to ensure that quality requirements of FAR 46.202 and 52.246 are communicated to the CO and to ensure that EPA-specific requirements (defined in EPA Order 5360.1 A2 and EPA Manual 5360 A1) are met. The QA Review Form (Appendix 46.1D), or other program-specific QA Review Form, shall be completed for all solicitations, contract statements of work, statements of work for work assignments/task orders/delivery orders, and modifications to existing work assignments/task orders/delivery orders that involve a significant change to the Statement of Work. Actions that do not effect the work performed by the contractor, e.g., incremental funding or time extensions, do not require a QA Review Form.

EPA Organizations' QA Managers may tailor this form, submit their tailored form to the Office of Environmental Information's Quality Staff for approval, and then incorporate their program-specific form into their Quality Management Plan after approval. Section III.b of Appendix 46.1D must be included in the tailored form in its entirety for solicitations although options that are not used by an organization may be listed as 'Not Applicable.' If an organization does not tailor the form, then the form provided in Appendix 46.1D must be used for all solicitations and contract actions.

### **46.1.5.2 Technical Evaluation Requirements**

If the QA Review Form indicates that quality requirements are applicable to a procurement and

- the potential value of the procurement exceeds \$500,000; or
- the estimate of the percentage of costs or level-of-effort allocated to activities requiring quality requirements exceeds 15%; or
- procedures defined in the Agency-approved Quality Management Plan of the organization sponsoring the work apply;

then the quality documentation (i.e., the Quality Management Plan or equivalent documentation) shall be required as part of the Technical Evaluation Criteria. The QA Manager, QA Officer, or authorized QA designee as defined in the Organization's Quality Management Plan, shall: (1) assist the Project Officer with development of the Technical Evaluation Criteria, and any associated technical instructions, for the Request for Proposal, and (2) serve as a member of the Technical Evaluation Panel for the purpose of evaluating the QA aspects of the technical proposals. Program Offices will establish procedures for QA Officer review of proposals on procurements of \$500,000 or less.

**46.1.5.3 Process****46.1.5.3.1 Directions for Contracting Officer's Representatives**

Directions for Contracting Officer's Representatives (CORs) are contained in Appendix 46.1A.

*Before award of contract (solicitations):* The CORs (i.e., Project Officers, Deputy Project Officers, Regional Project Officers, Zone Project Officers, Delivery Order Project Officers, Work Assignment Managers, Task Order Managers, Technical Program Managers) will use the directions in Appendix 46.1A to identify the quality requirements necessary for an acquisition, complete the QA Review Form, and provide this information to the CO.

*After award of a contract:* For each work assignment/task order/delivery order, or significant modification to the Statement of Work for existing work assignments/task orders/delivery orders, the CORs will use the directions in Appendix 46.1A to identify the quality requirements necessary, complete the QA Review Form, and incorporate the quality requirements into the Statement of Work for the work assignment/task order/delivery order.

**46.1.6.3.2 Directions for Contracting Officers**

Directions for COs are contained in Appendix 46.1B.

*Before award of contract (solicitations):* The CO will incorporate the quality requirements for the acquisition into the solicitation and contract using the QA Review Form provided by the COR (Appendix 46.1D), the directions provided in Appendix 46.1B, and the clause contained in Appendix 46.1C. The clause in Appendix 46.1C is contained in the Integrated Contract Management System (ICMS) database.

*After award of a contract:* The CO will use the directions in Appendix 46.1B to ensure that quality requirements conform to the requirements of the contract.

## APPENDIX 46.1A DIRECTIONS FOR CONTRACTING OFFICER'S REPRESENTATIVES

### Before Award of Contract

- STEP 1. Review the Statement of Work with the QA Manager (or the appropriate QA personnel<sup>1</sup>) to determine if QA requirements apply. If not, complete Sections I, IIa, and IV of the QA Review Form (Appendix 46.1D or an approved programspecific form provided by your QA Manager), and the remaining steps (before award of contract) do not apply.
- STEP 2. If QA requirements apply, determine what standards apply as allowed by your organization's Quality Management Plan (with the assistance of the QA Manager). Generally, ANSI/ASQC E4-1994 applies to the majority of EPA's work requiring higher-level contract quality requirements; however, standards other than ANSI/ASQC E4-1994 may apply depending on the nature of the work (for example, ISO 9001, ANSI/ASME NQA-1, etc.). If standards other than ANSI/ASQC E4-1994 apply, identify (with the assistance of the QA Manager) what documentation is required to determine conformance to these standards.
- STEP 3. Complete the QA Review Form (Appendix 46.1D or an approved programspecific form provided by your QA Manager) and obtain a concurrence signature of the QA Manager as part of the acquisition package.
- For each type of documentation selected in Section III.b of the QA Review Form, identify (with the assistance of the QA Manager) whether the documentation should be prepared in accordance with the standard EPA requirements [i.e., *EPA Requirements for Quality Management Plans (QA/R-2)* and *EPA Requirements for Quality Assurance Project Plans (QA/R-5)*] or whether other EPA-approved requirements will be used. The standard EPA requirements should be used unless the QA Manager agrees to different requirements identified in your organization's approved Quality Management Plan.
- STEP 4. If the potential value of the procurement exceeds \$500,000; or the estimate of the percentage of costs or level-of-effort allocated to activities requiring quality requirements exceeds 15%; or procedures defined in the Agency-approved Quality Management Plan of the organization sponsoring the work apply; then the quality documentation (i.e., the Quality Management Plan or equivalent documentation)

<sup>1</sup>Appropriate QA personnel are defined in each EPA organization's Agencyapproved Quality Management Plan. For simplicity, the use of the term QA Manager will refer to both the QA Manager and other approved QA personnel.

shall be included as part of the Technical Evaluation Criteria. The QA Manager, QA Officer, or authorized QA designee as defined in the organization's approved Quality Management Plan, shall : (1) assist the Project Officer with development of the Technical Evaluation Criteria, and any associated technical instructions, for the Request for Proposal, and (2) serve as a member of the Technical Evaluation Panel for the purpose of evaluating the QA aspects of the technical proposals when a Technical Evaluation Panel is convened.

**After Award of Contract** - Perform these steps for each Statement of Work under the contract.

**STEP 5.** Review the project and determine if it requires quality documentation (for example, a QA Project Plan). Incorporate the requirement to develop this documentation and to implement the EPA-approved documentation into the project's Statement of Work. If the project will be based on previously prepared and current EPA-approved quality documentation<sup>2</sup>, incorporate the requirement to implement this documentation into the project's Statement of Work.

**STEP 6.** Complete a QA Review Form (Appendix 46.1D or an approved program-specific form provided by your QA Manager) for each project and attach it to the project's Statement of Work (e.g., work assignment, delivery order, task order). Obtain a concurrence signature of the QA Manager.

<sup>2</sup>For policy on approval procedures and requirements for ensuring quality documentation is current, see Sections 5.2.1 and 5.2.2 of EPA Manual 5360 A1 (May 2000) and your organization's Quality Management Plan.

**APPENDIX 46.1B DIRECTIONS FOR CONTRACTING OFFICERS**

**STEP 1:** Review the QA Review Form (Appendix 46.1D) provided by the COR. If the COR has not provided a QA Review Form ask him/her to provide such form.

**STEP 2:** If the procurement requires higher-level quality assurance requirements, insert the contract clause in Appendix 46.1C into the simplified acquisition, solicitation, and/or contract, and select the appropriate documentation using Section III.b of the QA Review Form provided by the COR.

If standards other than ANSI/ASQC E4-1994 are identified by the COR in Section III.a.2 of the QA Review Form, insert these standards (and any tailoring) into the contract clause in Appendix 46.1C. Also, incorporate the following statement addressing the requirements for conforming to these standards:

“The following quality requirements apply to this work: \_\_\_\_\_”

**STEP 3:** Incorporate all approved QA documentation submitted by the contractor before award into the contract. Note: EPA may require that the Contractor revise the quality documentation after award of the contract, so verify with the COR that the documentation has been approved before incorporating it into the contract.

**STEP 4:** **After award of the contract,** review the QA Review Form and any quality assurance requirements and information provided by the COR for each Statement of Work performed under the contract. Ensure that these requirements are consistent with the quality requirements of the contract.

**APPENDIX 46.1C CONTRACTS CLAUSE AND TAILORING LANGUAGE Do**

*not incorporate the instructions in brackets [ ] into the solicitation and contract.* Higher-

Level Contract Quality Requirement (FAR 52.246-11) (Feb 1999).

*[Contracting Officer (CO), incorporate the following language into all solicitations and contracts that require higher-level quality standards using the QA Review Form provided by the Contracting Officer's Representative (COR). Include any other quality standards identified by the COR on the QA Review Form.]*

The Contractor shall comply with the higher-level quality standard selected below.

	<b>Title</b>	<b>Numbering</b>	<b>Date</b>	<b>Tailoring</b>
↕	⊃ <i>Specifications Quality Systems for Environmental Data Collection and Environmental Technology Programs</i>	ANSI/ASQC E4	1994	See below.
↕				
↕				

As authorized by FAR 52.246-11, the higher-level quality standard ANSI/ASQC E4 is tailored as follows:

The solicitation and contract require the offeror/contractor to demonstrate conformance to ANSI/ASQC E4 by submitting the quality documentation described below.

In addition, after award of the contract, the Contractor shall revise, when applicable, quality documentation submitted before award to address specific comments provided by EPA and submit the revised documentation to the Contracting Officer's Representative.

After award of the contract, the Contractor shall also implement all quality documentation approved by the Government and specified under this contract.

- A. *[CO, select the appropriate documentation using information provided by the COR and then insert the following into the solicitation and contract.]*

**Quality Documentation:** The offeror must submit the following quality system documentation:

**Before Award Documentation**

1. Documentation of an organization's Quality System: Either >>>QMP developed in accordance with R2 or >>>Other: \_\_\_\_\_  
 \_\_\_\_\_ Combined documentation of an organization's Quality System and application of QA and QC activities to the single project covered by the contract: Either developed in accordance with >>>R-2 and R-5 or >>>Other: \_\_\_\_\_
2. Programmatic QA Project Plan. Either developed in accordance with R-5 \_\_\_\_\_  
 or >>>Other: \_\_\_\_\_  
 \_\_\_\_\_ Application of QA and QC activities to the single project covered
3. by contract: Either >>>QA Project Plan developed in accordance with R-5 or  
 >>>Other:  
 Not applicable.

**After Award Documentation**

4. Documentation of an organization's Quality System: Either >>>QMP developed in accordance with R2 or >>>Other: \_\_\_\_\_  
 Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract: Either developed in accordance with >>>R-2 and R-5 or  
 >>>Other: \_\_\_\_\_  
 Not applicable.
- Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with >>>R-5; >>>A supplement to the following Programmatic QA Project Plan \_\_\_\_\_ ; or

>>>Other:\_\_\_\_\_

Programmatic QA Project Plan with supplements for each specific project:  
Developed in accordance with: \_\_\_\_\_ Existing

documentation of the application of QA and QC activities will be used: Either >>>

Documentation developed pre-award; >>>Documentation will be identified in

individual statements of work; or >>>Documentation  
identified in Section \_\_\_\_\_ of the Statement of Work

- B. *[PRE-AWARD TAILORING LANGUAGE: CO, insert the following paragraph into the solicitation and contract.]*

**Pre-award Documentation:** The offeror must submit the documentation identified above as “Before Award” as a separate and identifiable part of its technical proposal. This documentation will be prepared in accordance with the requirements identified above [R-2 refers to *EPA Requirements for Quality Management Plans* (EPA/240/B-01/002); R-5 refers to *EPA Requirements for QA Project Plans* (EPA/240/B-01/003)]. The offeror shall describe their plan for covering the costs associated with the required documentation. Work involving environmental data generation or use shall not commence until the Government has approved this documentation and incorporated it into the contract.

- C. *[POST-AWARD TAILORING LANGUAGE: CO, insert the following three paragraphs into the solicitation and contract.]*

**Post-award Documentation:** The Contractor shall submit the quality system documentation identified above as “After Award” to the Contracting Officer’s Representative following issuance of applicable statements of work.

This documentation will be prepared in accordance with the requirements identified above [R-2 refers to *EPA Requirements for Quality Management Plans* (EPA/240/B-01/002); R-5 refers to *EPA Requirements for QA Project Plans* (EPA/240/B-01/003)]. The offeror shall describe their plan for covering the costs associated with the required documentation.

The Government will review and return the quality documentation, with comments, and indicate approval or disapproval. If the quality documentation is not approved, the contractor shall revise the documentation to address all comments and shall submit the revised documentation to the government for approval.

The Contractor shall not commence work involving environmental data collection, generation, use or reporting until the Government has approved the quality documentation.

## APPENDIX 46.1D U.S. EPA QUALITY ASSURANCE REVIEW FORM FOR CONTRACT ACTIONS

### I. General Information

#### a. Vehicle Type:

☐ Solicitation/Sole Source (RFP #: \_\_\_\_\_ )

☐ Delivery Order/Work Assignment /Task Order  
(SOW #: \_\_\_\_\_ and Contract #: \_\_\_\_\_ )

#### b. Descriptive Title:

c. Sponsoring Organization (e.g., Branch, Division, Office, etc.):      d. Project Duration:

e. Is this a new ☐ or continuation of an existing ☐ project?

### II. Scope of Work

[For example activities, see [www.epa.gov/quality/examples.html](http://www.epa.gov/quality/examples.html).]

- | a. Does the work involve:  | Yes | No  |
|--|-----|-----|
| <ul style="list-style-type: none"> <li>• the collection, generation, use and/or reporting of environmental data?<br/>(Environmental data are defined as any measurements or information that describe environmental processes, location, or conditions; ecological or health effects and consequences; or the performance of environmental technology. For EPA, environmental data include information collected directly from measurements, produced from models, and compiled from other sources such as data bases or the literature.)</li> </ul> | [ ] | [ ] |
| <ul style="list-style-type: none"> <li>• design, construction, and/or operation of environmental technologies?</li> </ul>  | [ ] | [ ] |
| <ul style="list-style-type: none"> <li>• development and/or use of models?</li> </ul>  | [ ] | [ ] |
| <ul style="list-style-type: none"> <li>• other activities that need quality assurance or quality control requirements as identified in your organization's Quality Management Plan? If yes, list: _____</li> </ul>   | [ ] | [ ] |

***If all answers are No, skip Section III and complete Section IV.***

- b. Estimate of percentage of costs or level-of-effort allocated to the activities identified above: %.

*Quality-Related Requirements*

*(Where applicable, reference a specific section of the Statement of Work.)*

*For Solicitations Only (complete (b) - (~ below, as well)*

1. *Insert the percentage of technical evaluation points assigned to offeror's quality system documentation, or P/F if the evaluation is pass/fail: \_\_\_\_\_*
2. *List any quality standards (from your organization's Quality Management Plan) that you will use in lieu of, or in addition to, Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs (ANSI/ASQC E4). These standards are*

*Title:*

*Numbering:*

*Date:*

*Requirements (Tailoring):*

- b. *QA Documentation Options: (For solicitations, complete items 1-4; for all actions other than solicitations, complete items 3-4. All documentation specified under "Other" must be defined in your organization's Quality Management Plan and be consistent with requirements defined in EPA Manual 5360 A1. For items checked under #2, there must be adequate information in the SOW for the offeror to develop this documentation.)*

*Before Award Documentation*

1. *Documentation of an organization's Quality System: Either o QMP developed in accordance with R-2 or o Other: \_\_\_\_\_  
Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by contract:  
Either developed in accordance with o R-2 and R-5 or o Other:*
2. *Programmatic QA Project Plan: Either developed in accordance with RS or o Other:*

<sup>1</sup>*QMP refers to a Quality Management Plan. Programmatic QA Project Plan refers to a QA Project Plan that would cover multiple projects with similar activities. R-2 refers to EPA Requirements for Quality Management Plans (QA/R-2) (EPA/240/B-01/002, 03/20/01) and R-5 refers to EPA Requirements for Quality Assurance Project Plans (QA/R-5) (EPA/240/B-01/003, 03/20/01) - copies of these documents are available at [www.epa.gov/quality](http://www.epa.gov/quality).*

Application of QA and QC activities to the single project covered by contract:

Either >>>QA Project Plan developed in accordance with R-5 or

>>>Other: \_\_\_\_\_

Not applicable.

### **After Award Documentation<sup>1</sup>**

3. Documentation of an organization's Quality System: Either >>>QMP

developed in accordance with R-2 or >>>Other: \_\_\_\_\_

Combined documentation of an organization's Quality System and application of QA and QC to the single project covered by the contract:

Either developed in accordance with >>>R-2 and R-5 or >>>Other:

Not applicable.

4. Documentation of the application of QA and QC activities to applicable project(s): Either developed in accordance with >>>R-5; >>>A supplement to the following Programmatic QA Project Plan \_\_\_\_\_ ; or

>>>Other: \_\_\_\_\_

Programmatic QA Project Plan with supplements for each specific project:

Developed in accordance with: \_\_\_\_\_ Existing documentation of the application of QA and QC activities will be used: Either

>>>Documentation developed pre-award; >>>Documentation will be identified

in individual Statements of Work or >>>Documentation

identified in Section \_\_\_\_\_ of the Statement of Work.

- c. Reports:** Are quality reports or reports containing quality assurance information (for example, status of quality system implementation, review of a quality system, quality control data, etc.) required? ☐ **Yes** ☐ **No**

If yes, identify the required reports and the time frame for submission:

- d. Assessments:** Select all quality assessments that will be performed either pre-award or post-award:

	Pre-Award	Post Award
On-site evaluation of offeror's/contractor's facility		
Assessments of the offeror's/contractor's Quality System (e.g., quality system audits, management system reviews, etc.)		

DOCUMENT OBSOLETE

Project-specific assessments (e.g., technical systems audits, surveillance, performance evaluations, data quality assessments, peer reviews, readiness reviews)

For each assessment, specify type, date to perform, and who will perform it (if known):

- e. **Procedures to Update Documentation:** Identify any procedures/requirements for updating EPA-approved quality-related documentation:
- f. **Other Requirements:** Identify any other pertinent quality-related requirements (as identified in your organization's Quality Management Plan): \_\_\_\_\_

**IV. The signatures below verify that the Statement of Work has been reviewed to ascertain if quality assurance or quality control activities are needed and that the appropriate quality requirements have been established.**

Contracting Officer's Representative

Date

Quality Assurance Manager

Date